UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 19, 2004

MEMORANDUM

Subject: Efficacy Review for Surfacine® All-Purpose Cleaner, EPA Reg. No. 71661-1; DP Barcode: D297029

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510C)

Thru: Michele E. Wingfield, Chief
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To: Lisa McKelvin / Adam Heyward
Regulatory Management Branch II
Antimicrobials Division (7510C)

Applicant: Intelligent Biocide, LLC
One Industrial Way
Tyngsboro, MA 01879

Formulation from the Label:

Active Ingredient	% by wt.
Silver	0.0095 %
Poly(hexamethylenebiguanide)hydrochloride	0.5600 %
Other Ingredients:	99.4305 %
Total	100.0000 %

I. BACKGROUND

The product, Surfacine® All-Purpose Cleaner (EPA Reg. No. 71661-1), is an EPA-approved disinfectant (bactericide, fungicide) for use on hard, non-porous surfaces in household, institutional, commercial, animal care, and hospital or medical environments. The applicant requested an amendment to the registration of this product to add claims for effectiveness against additional microorganisms, specifically Human coronavirus and Canine parvovirus. The applicant also requested an update of their label to reflect effectiveness of the product at a 1 minute contact time against *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, and *Staphylococcus aureus*. In addition, the applicant requested an update of their label to reflect residual effectiveness of the product for 24 hours. Studies were conducted at Lonza Inc., located at 79 Route 22 East, Annandale, NJ 08801; and MicroBioTest, Inc., located at 105B Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant's agent to EPA (dated September 17, 2003), EPA Form 8570-1 (Application for Pesticide), nine studies (MRID Nos. 461144-01 and 460809-02 through 460809-09), Statements of No Data Confidentiality Claims for all nine studies, and the proposed label.

II. USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as stove tops, sinks, drain boards, cabinets, appliance exteriors, floors, counter tops, tubs, showers, toilets, walls, telephones, doorknobs, pet areas, garbage cans, desks, and painted woodwork. Directions on the proposed label provided the following information regarding use of the product as a disinfectant: Pre-clean surfaces. Spray the product at a distance of 6-8 inches from surfaces until thoroughly wet. Surfaces must remain wet for 1 minute. [Surfaces must remain wet for 5 minutes when disinfecting against Canine parvovirus.] [Surfaces must remain wet for 10 minutes when disinfecting against *Trichophyton mentagrophytes*.] Wipe surfaces dry after treatment. Rinse food contact surfaces with potable water before reuse. Do not use on glasses, dishes or utensils as a disinfectant.

The product is also designed to be used as a sanitizer on non-food contact surfaces. Directions on the proposed label provided the following information regarding use of the product as a sanitizer: Pre-clean surfaces. Spray the product at a distance of 6-8 inches until surfaces are thoroughly wet. Surfaces must remain wet for 10 minutes. Allow to air dry.

III. AGENCY STANDARD FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). **Performance requirements:** To support products represented in labeling as "disinfectants", killing

on 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level. The above Agency standards are presented in DIS/TSS-1.

Residual Self-Sanitizing Activity on Non-Food Contact Surfaces: The effectiveness of products that provide self-sanitizing activity on treated surfaces that are likely to become and remain wet under normal conditions of use must be supported by data derived using a controlled in-use study or simulated in-use study. A study such as EPA Protocol #01-1A, Protocol for Residual Self-Sanitizing Activity of Dried, Chemical Residues on Hard, Non-Porous Surfaces, may be used. EPA Protocol #01-1A includes a regimen where each treated surface undergoes specific wear exposures to demonstrate residual efficacy of the product. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label. The testing conditions (e.g., temperature, relative humidity) must be the same as those likely to be encountered under normal conditions of product use. **Performance requirements:** Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. The starting inocula of the challenge microorganisms (for initial and subsequent challenges) must be of sufficient concentration to provide at least 10^4 survivors on the parallel control surface. The above Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(n).

EPA Protocol #01-1A does not specify the number of product lots or the organisms that must be tested; however, DIS/TSS-10 standards for sanitizers for non-food contact surfaces require testing of 3 product samples, representing 3 different batches, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038).

Virucidal requirements: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of the AOAC Use-Dilution Method (for liquid disinfectants) must be used in developing data for virucides intended for use upon dry inanimate, environmental surfaces (e.g., floors, tables, cleaned dried medical instruments). To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. **Performance standard:** For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Supplemental Recommendations: An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5% blood serum. The organic soil level suggested is considered appropriate for simulating lightly or moderately soiled surface conditions. When the surface to be treated has heavy soil deposits, a cleaning step must be

recommended prior to application of the antimicrobial agent. The effectiveness of antimicrobial agents must be demonstrated in the presence of a specific organic soil at an appropriate concentration level when specifically claimed and/or indicated by the pattern of use. The hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish disinfectant efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. All products tested by the recommended methods may be tested at the exposure periods prescribed in those methods. When an antimicrobial agent is intended to be effective in treating a non-porous surface, the Recommended Methods simulate this condition by using non-porous surface carrier (stainless steel cylinder or glass slide) specified in the method. The exposure period or manner of use necessary to provide efficacy must be featured prominently on the product label. These Agency standards are presented in DIS/TSS-2.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 461144-01 "Surfacine® All Purpose Cleaner: Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-porous Surfaces," by Andy Kaziska. Study conducted at Lonza Inc. Study completion date – August 21, 2003. Study Protocol Number SP-03091-M.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 130013, 130074, and 130075) of the product, Surfacine® All-Purpose Cleaner, were tested using EPA Protocol #01-1A, Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces (copy provided). At least one product lot (i.e., Lot 130013) was at least 60 days old at the time of testing. The product was received ready-to-use. Four one-inch square glass carriers per organism per product lot were inoculated with 10 µL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30-35 minutes at 35±2°C. Each carrier was sprayed with the product from a distance of 6-10 inches. The carriers were allowed to dry completely at room temperature and 45-55% relative humidity. A series of 12 wear cycles of 4-5 seconds with 5 reinoculations with 10 µL of 18-24 hour old cultures was performed over a 24-hour period. This was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 10 minutes, the carriers were transferred to 30 mL of D/E neutralizing broth, sonicated for 20±2 seconds, and agitated for 3-4 minutes at 250 rpm. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48-54 hours at 30±2°C for *Enterobacter aerogenes* and at 35±2°C for *Staphylococcus aureus*. Colonies then were counted. Controls included numbers controls, sterility, and neutralization. The reported average colony forming units per carrier, for each test microorganism, are as follows:

Staphylococcus aureus	**1.2×10^5**
Enterobacter aerogenes	**4.6×10^5**

Note: The study was conducted according to GLP standards with the following exception: The stability of the product lots used under storage conditions was not determined (40 CFR Part 160.105).

Note: The applicant provided the data for a failed neutralization confirmation test. In that test, the recovery of the challenge organism was above the specified limit of the procedure. Thus, the test was invalid. These data were not used to support efficacy of the test product. The neutralization confirmation test was repeated with acceptable results. See Section 6.2.2 of the laboratory study.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

2. MRID 460809-02 "AOAC Germicidal Spray Test Using *Pseudomonas aeruginosa*" for Surfacine® All-Purpose Cleaner, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – September 5, 2003. Amended final report date – September 5, 2003. Laboratory Project Identification Number 163-301.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One lot (Lot No. 120151) of the product, Surfacine® All-Purpose Cleaner, was tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. The product lot was at least 60 days old at the time of testing. The product was received ready-to-use. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30-40 minutes at 37±2°C. Each carrier was sprayed with the product from a distance of 6-8 inches until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20±1°C. Excess liquid was allowed to drain and the carriers were transferred to tubes of Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included viability, dried carrier counts, neutralizer effectiveness, bacteriostasis, confirmation of challenge organism, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Pseudomonas aeruginosa* 4.7x 10^5**.

Note: The original report, dated February 3, 2003, was amended to include the correct active ingredient of the product.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

3. MRID 460809-03 "AOAC Germicidal Spray Test Using *Pseudomonas aeruginosa*" for Surfacine® All-Purpose Cleaner, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – September 5, 2003. Amended final report date – September 5, 2003. Laboratory Project Identification Number 163-307.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One lot (Lot No. 120150) of the product, Surfacine® All-Purpose Cleaner, was tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of

Analysis, 16th Edition, 1995. The product lot was at least 60 days old at the time of testing. The product was received ready-to-use. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30-40 minutes at 37±2°C. Each carrier was sprayed with the product from a distance of 6-8 inches until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20±1°C. Excess liquid was allowed to drain and the carriers were transferred to tubes of Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included viability, dried carrier counts, neutralizer effectiveness, bacteriostasis, confirmation of challenge organism, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Pseudomonas aeruginosa*** **1.9 x 10^5**.

Note: The original report, dated February 19, 2003, was amended to include the correct active ingredient of the product.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

4. MRID 460809-04 "AOAC Germicidal Spray Test Using *Pseudomonas aeruginosa*" for Surfacine® All-Purpose Cleaner, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – September 5, 2003. Amended final report date – September 5, 2003. Laboratory Project Identification Number 163-308.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). One lot (Lot No. 130013) of the product, Surfacine® All-Purpose Cleaner, was tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. The product was received ready-to-use. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30-40 minutes at 37±2°C. Each carrier was sprayed with the product from a distance of 6-8 inches until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20±1°C. Excess liquid was allowed to drain and the carriers were transferred to tubes of Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included viability, dried carrier counts, neutralizer effectiveness, bacteriostasis, confirmation of challenge organism, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Pseudomonas aeruginosa*** **1.9 x 10^5**.

Note: The original report, dated February 19, 2003, was amended to include the correct active ingredient of the product.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

5. MRID 460809-05 "AOAC Germicidal Spray Test Using *Staphylococcus aureus*" for Surfacine® All-Purpose Cleaner, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – September 5, 2003. Amended final report date – September 5, 2003. Laboratory Project Identification Number 163-309.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot No. 120151) of the product, Surfacine® All-Purpose Cleaner, was tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. The product lot was at least 60 days old at the time of testing. The product was received ready-to-use. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30-40 minutes at 37±2°C. Each carrier was sprayed with the product from a distance of 6-8 inches until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20±1°C. Excess liquid was allowed to drain and the carriers were transferred to tubes of Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included viability, dried carrier counts, neutralizer effectiveness, bacteriostasis, confirmation of challenge organism, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Staphylococcus aureus* 9.7 x 10^5**.

Note: The original report, dated February 19, 2003, was amended to include the correct active ingredient of the product.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

6. MRID 460809-06 "AOAC Germicidal Spray Test Using *Staphylococcus aureus*" for Surfacine® All-Purpose Cleaner, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – September 5, 2003. Amended final report date – September 5, 2003. Laboratory Project Identification Number 163-320.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot No. 120150) of the product, Surfacine® All-Purpose Cleaner, was tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. The product lot was at least 60 days old at the time of testing. The product was received ready-to-use. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30-40 minutes at 37±2°C. Each carrier was sprayed with the product from a distance of 6-8 inches until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20±1°C. Excess liquid was allowed to drain and the carriers were transferred to tubes of Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included viability, dried carrier counts, neutralizer effectiveness, bacteriostasis, confirmation of challenge organism, and sterility. The reported average colony forming units per carrier, for the test microorganism, is:

***Staphylococcus aureus* 7.3 x 10^5.**

Note: The original report, dated February 12, 2003, was amended to include the correct active ingredient of the product.

7. MRID 460809-07 "AOAC Germicidal Spray Test Using *Staphylococcus aureus*" for Surfacine® All-Purpose Cleaner, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – September 5, 2003. Amended final report date – September 5, 2003. Laboratory Project Identification Number 163-321.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). One lot (Lot No. 130013) of the product, Surfacine® All-Purpose Cleaner, was tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. The product was received ready-to-use. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. The carriers were dried for 30-40 minutes at 37±2°C. Each carrier was sprayed with the product from a distance of 6-8 inches until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20±1°C. Excess liquid was allowed to drain and the carriers were transferred to tubes of Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included viability, dried carrier counts, neutralizer effectiveness, bacteriostasis, confirmation of challenge organism, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Staphylococcus aureus* 7.3 x 10^5.**

Note: The original report, dated February 12, 2003, was amended to include the correct active ingredient of the product.

8. MRID 460809-08 "AOAC Germicidal Spray Test Using *Salmonella choleraesuis*" for Surfacine® All-Purpose Cleaner, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – September 5, 2003. Amended final report date – September 5, 2003. Laboratory Project Identification Number 163-328.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708). Three lots (Lot Nos. 120150, 120151, and 130013) of the product, Surfacine® All-Purpose Cleaner, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. At least two of the product lots (i.e., Lot Nos. 120150 and 120151) were at least 60 days old at the time of testing. The product was received ready-to-use. Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers were inoculated with 0.01-0.03 mL of a 48-54 hour old suspension of the test organism. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier was sprayed with the product from a distance of 6-8 inches until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20±1°C. Excess liquid was allowed to drain and

the carriers were transferred to tubes of Letheen Broth containing 7% Polysorbate 80 and 1% Lecithin to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included viability, dried carrier counts, neutralizer effectiveness, bacteriostasis, confirmation of challenge organism, and sterility. The reported average colony forming units per carrier, for the test microorganism, is: ***Salmonella choleraesuis*** **5.2 x 10^5**.

Note: The original report, dated March 10, 2003, was amended to include the correct active ingredient of the product.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

9. MRID 460809-09 "Virucidal Effectiveness Test, Coronavirus" for Surfacine® All Purpose Cleaner, by M. Khalid Ijaz. Study conducted at MicroBioTest, Inc. Study completion date – September 5, 2003. Amended final report date – September 5, 2003. Laboratory Project Identification Number 163-355.

This study was conducted against the Human coronavirus (Strain not specified; ATCC VR-740), using MRC-5 cells (obtained from Diagnostics Hybrids, Inc., Athens, OH) as the host system. Two lots (Lot Nos. 120150 and 120151) of the product, Surfacine® All-Purpose Cleaner, were tested according to a MicroBioTest protocol entitled "Virucidal Effectiveness Test Coronavirus" (dated April 28, 2003; copy provided). ASTM Method E1053-97 was referenced. The stock virus titer contained a 5% organic soil load (serum not specified). The product was received ready-to-use. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at room temperature for 30-60 minutes. For each lot of product, separate dried virus films were exposed to 2.0 mL of the product. The virus films remained exposed to the product for 1 minute at 20±2°C. After exposure, the carriers were neutralized with 2.0 mL of fetal bovine serum containing 0.1% $NaSO_2C_2H_3$. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephacryl column, and diluted serially in Eagle's Minimum Essential Medium supplemented with 10% fetal bovine serum (CCM). MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with an unspecified aliquot of the dilutions. The cultures were incubated at 33±1°C for 90-120 minutes for viral adsorption. Post-adsorption, the plates were washed once with Earle's balanced salt solution and re-fed with CCM. The cultures were incubated for 10-14 days at 33±1°C in 5±1% CO_2. Post-incubation, unspecified cytopathic effects were scored. Controls included viability, plate recovery, column titer, cytotoxicity, virus stock titer, and neutralizer effectiveness. The 50% cell culture infectious dose ($CCID_{50}$/ mL) was determined by the method of Reed and Muench. The titer of the dried virus control was **5.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was ≥**3.0 $\log_{10}$** for both batches.

Note: The original report, dated June 20, 2003, was amended to include the correct active ingredient of the product.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be

acceptable.

V. RESULTS

MRID Number	Organism	Lot No.	Geometric Mean of Test Survivors (CFU/carrier)	Geometric Mean of Control Survivors (CFU/carrier)	Percent Reduction
461144-01	*Staphylococcus aureus*	130013	≤82	1.2×10^5	99.93
		130074	≤70		99.94
		130075	≤47		99.96
	Enterobacter aerogenes	130013	≤30	4.6×10^5	>99.99
		130074	≤30		>99.99
		130075	≤54		99.99

MRID Number	Organism	No. Exhibiting Growth/Total No. Tested			Dried Carrier Count (CFU/carrier)
		Lot No. 120151	Lot No. 120150	Lot No. 130013	
460809-02	*Pseudomonas aeruginosa*	0/60	---	---	4.7×10^5
460809-03	*Pseudomonas aeruginosa*	---	0/60	---	1.9×10^5
460809-04	*Pseudomonas aeruginosa*	—	---	0/60	1.9×10^5
460809-05	*Staphylococcus aureus*	0/60	---	---	9.7×10^5
460809-06	*Staphylococcus aureus*	---	0/60	---	7.3×10^5
469809-07	*Staphylococcus aureus*	---	---	0/60	7.3×10^5
469809-08	*Salmonella choleraesuis*	0/60	0/60	0/60	5.2×10^5

MRID Number	Organism	Results			Plate Recovery Control ($CCID_{50}$/ mL)
			Lot No. 120150	Lot No. 120151	
460809-09	Human coronavirus	10^{-2} dilution	Cytotoxicity	Cytotoxicity	$10^{5.5}$
		10^{-3} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$CCID_{50}$/mL	$\leq 10^{2.5}$	$\leq 10^{2.5}$	
		Log reduction	≥ 3.0 $\log_{10}$	≥ 3.0 $\log_{10}$	

VI. CONCLUSIONS

1. The submitted efficacy data (MRID No. 461144-01) **support** the use of the product, Surfacine® All-Purpose Cleaner, as a sanitizer with 24-hour residual bactericidal activity when tested against *Staphylococcus aureus* and *Enterobacter aerogenes*. A >99.9% reduction in population was observed when an 18-24 hour old inoculum was applied to carriers treated 24 hours previously. Numbers controls were at least 10^4. Neutralization confirmation testing showed positive growth of the organisms. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of the product, Surfacine® All-Purpose Cleaner, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load (heat-inactivated horse serum) for a contact time of 1 minute:

Pseudomonas aeruginosa	MRID Nos. 460809-02 through 460809-04
Salmonella choleraesuis	MRID No. 460809-08
Staphylococcus aureus	MRID Nos. 460809-05 through 460809-07

No growth was observed in the subcultures of the required number of carriers tested against the required number of product lots (i.e., three). At least one of the three product lots tested was at least 60 days old at the time of testing. Dried carrier counts were at least 10^4. Neutralizer effectiveness testing showed positive growth of the organisms. Viability controls were positive for growth. Sterility controls did not show growth.

3. The submitted efficacy data (MRID No. 460809-09) **support** the use of the product, Surfacine® All-Purpose Cleaner, as a disinfectant with virucidal activity against the Human coronavirus on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute. Cytotoxicity was observed at the 10^{-2} dilution. Complete inactivation (no growth) was indicated in

all higher dilutions. A log reduction of >3.0 was demonstrated. A recoverable virus titer of 10^{-4} was achieved.

VII. RECOMMENDATIONS

1. The proposed label claims (as supported by MRID No. 461144-01) **are acceptable** regarding the use of the product, Surfacine® All-Purpose Cleaner, as a residual sanitizer against *Enterobacter aerogenes* and *Staphylococcus aureus* on hard, non-porous surfaces after an elapsed time of 24 hours.

2. The proposed label claims **are acceptable** regarding the use of the product, Surfacine® All-Purpose Cleaner, as a disinfectant against the following microorganisms on hard, non-porous surfaces for a contact time of 1 minute:

Pseudomonas aeruginosa	MRID Nos. 460809-02 through 460809-04
Salmonella choleraesuis	MRID No. 460809-08
Staphylococcus aureus	MRID Nos. 460809-05 through 460809-07
Human coronavirus	MRID No. 460809-09

3. The proposed label [see page 2 of the proposed label] now includes "**Cause of Ringworm**" in describing the organism, *Trichophyton mentagrophytes*. Ringworm is caused by several different fungi; it would be more accurate for the label to state: "**A cause of ringworm**" or "**A cause of ringworm of the foot.**"

4. New language on the label states that the product "**kills greater than 99.999% of Pseudomonas aeruginosa** . . . ." This is a claim regarding the effectiveness of the product as a disinfectant, and should be revised so that it reads "**kills greater than 99% of Pseudomonas aeruginosa** . . . ."

5. Under the "Veterinary Practice. . ." section of the proposed label [see page 4 of the proposed label], the applicant should revise the phrase "equipment used for animal food and water" so that it reads, "equipment not used for animal food and water." The product is not to be used to disinfect surfaces or items from which humans and animals eat and drink.

6. Remove highchairs from the list of items that can be disinfected. Highchair table tops are considered food contact surfaces. Also, revise "microwave ovens" to read, "exteriors of microwave ovens."